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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1631	

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12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/724,928	FODOR ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/07;6/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 57-61,63-69,71-82,84-90,92-98,100,101,106-109,111-113,115-120,123-125,129-132,135,136,141-144,149,151,152,154 and 156-175.

Continuation of Disposition of Claims: Claims rejected are 57-61,63-69,71-82,84-90,92-98,100,101,106-109,111-113,115-120,123-125,129-132,135,136,141-144,149,151,152,154 and 156-175.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05 June 2007 and 03 October 2007 was filed after the mailing date of the first action on merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner to the extent possible.

Claim Status

Claims 57-61, 63-69, 71-82, 84-90, 92-98, 100-101, 106-109, 111-113, 115-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152,154, and 156-175 are pending.

Claims 1-56, 62, 70, 83, 91, 99, 102-107, 110, 114, 121-122, 126-128, 133-134, 137-140, 145-148, 150, 153, and 155 are cancelled.

Claims 173-175 are newly added.

Claims 57-61, 63-69, 71-82, 84-90, 92-98, 100-101, 106-109, 111-113, 115-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152,154, and 156-175 are being examined.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Response to Arguments

Applicant's arguments, see remarks p. 16, filed 24 May 2007, with respect to the objection to claims 151 and 154 as being substantial duplicates have been fully considered and are persuasive. The objection to claims 151 and 154 has been withdrawn.

Claim Rejections - 35 USC § 112, 2nd Paragraph

Applicant's arguments, see remarks p. 16, filed 24 May 2007, with respect to the rejection of claim 77 under 35 USC 112, 2nd paragraph have been fully considered and are persuasive. The rejection of 77 has been withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

Applicant's arguments, see remarks p. 17, filed 24 May 2007, with respect to the rejection of claims 163-172 under 35 USC 112 1st paragraph have been fully considered and are persuasive. The rejection of claims 163-172 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 57-59, 65-67, and 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Shack et al (Journal of Histochemistry and Cytochemistry, Vol. 27, No. 1, p. 153-159, 1979).

The claims are directed to a computer program, computer software and a system for acquiring data from an array of polymers by: scanning, in which a scan stage is moved, a plurality of diverse polymers, each a polymer having a different sequence and localized in an area of less than 25,000 μm^2 and a density of more than 400 polymers/cm^2; receiving pixel data; collecting pixel data; storing the data in file and displaying the data.

Shack et al. describe a computerized system in which a the stage of a microscope is moved in an automated manner (abstract, lines 5-6) to image epithelial cells attached to a glass microscope slide (abstract lines 1-4), reading on an array of polymers. Shack et al teach that epithelial cells vary in size between 40 and 100 μm in diameter which corresponds to an area of 7850 μm^2 at the maximum cell diameter (p. 154, col. 1, para. 4, lines 4-5). Since each cell would be localized to a distinct location of the microscope slide, the cells read on the limitations of localized areas less than 25,000 μm^2. Furthermore, since cells are composed of polymers, the cells also read on the limitations of polymers and on the polymer densities of more than 400 polymers per cm^2. Shack et al teach receiving of the pixel data from the sample on the array as collecting data at a spatial sampling distance of 0.5 μm which is being read as teach the size of a single pixel using a photomultiplier tube (p. 157, col. 2, para. 3, line 2). The

light intensity obtained by the photomultiplier tube is collected (p. 157, col. 1, para. 2, line1), stored (p.157, col. 2, para. 4, lines 9-11) and displayed (p.154, col. 2, para.3, line2).

Response to Arguments

Applicant's arguments filed 24 May 2007 have been fully considered but they are not persuasive. Applicant argues that the substrate would not contain at least 400 diverse polymers per cm^2. The argument is not persuasive. Epithelial cells have more than 400 diverse polymers on their surface. As evidence of this fact, Holt et al have recently demonstrated in a proteomics based approach that at least 839 unique peptides and 276 unique proteins were identified from the cell membrane of epithelial cells. Thus inherently the epithelial cells of Shack would have had at least the 839 peptides and 276 proteins identified in the epithelial membrane by Holt et al.

Applicant's arguments, see remarks p. 18, filed 24 May 2007, with respect to the rejection of claims 57, 65, 73, 78, 86, 94, 108, 120, 132, and 144 as anticipated by Southern have been fully considered and are persuasive. The rejection of Southern has been withdrawn. The rejection is being withdrawn because Southern does not explicitly recite the claimed limitations of a substrate having 400 diverse polymers per cm^2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (WO 1989/10977), in view of Rushbrooke et al (WO 1988/04045).

The claims are directed to computer programs, computer softwares, and systems for performing methods comprising: inputting a plurality of data indicative of binding between polymers on a substrate and ligands in a sample solution in which the data are signal intensity versus position on the substrate and the polymers on the substrate are further localized to discreet areas that smaller than 2.5x105 microns^2; creating a image of the signal intensity versus position; and displaying the image to a user.

Southern et al teaches the construction, use, and analysis of arrays of nucleic acid polymers immobilized on a glass microscope slide substrate. The immobilized

polymers of Southern et al are immobilized in areas of less than 2.5x105 μm^2, specifically 100μm^2 cells (p. 11, lines 25-26). The number of molecules located in the localized area is $3x10^{-12}$ μmol per 100μm^2 (p. 12, lines 31-32), that is $18x\ 10^5$ molecules/100 μm^2 which is greater than the instantly claimed polymer density 10, 000 polymers per cm^2. Example 4 of southern, demonstrates the binding of ligand in solution (p. 20, line 3) to the polymers immobilized on the substrate (p. 20, line 3-4) to generate data indicative of binding (p. 20, lines 10-12). Southern et al. suggest that fluorescence signal (p. 14, lines 13-15) can also be used and that the process of data acquisition and analysis could be auto mated by computer systems programs and software (p. 14, lines 17-18 and 27-29).

Southern et al do not teach a system computer program or computer software used for inputting data from an array of nucleic acids based photon counts from fluorescence intensity.

However, Southern et al motivates one of skill in the art to combine the methods use and detection of immobilized polymers with a computerized scanning system (p. 14, lines 17-29).

Rushbrooke et al describe computer program, computer software and system in which input data relating to signal intensity versus position (p. 5, lines 16-20) are used to create an image of the signal intensity versus position (i.e. scanning) (p. 6, lines 21-24) that is displayed to a user (p. 6, lines 8-10). The system of Rushbrooke et al utilizes a microscope to input data (p.5, line 3). Rushbrooke et al teach the signal is fluorescence intensity (p. 4, lines 10-12) based on photon counts (p. 3, line 3).

Rushbrooke et al. shows that the system has an overall resolution of about 30 microns by 30 microns (p. 7, para.3 line 2-3).

It would have been obvious to one of ordinary skill in the art to combine the system and software for signal data acquisition and analysis of Rushbrooke et al with microscope slide microarrays of Southern et al because Rushbrooke et al teach a high sensitivity optical imaging system allowing the detection of low light levels for measurement of very small quantities of light emitted by diagnostic samples (p. 1, lines 1-6) and applicability of their invention to fluorescence microscopy and x-ray digital imaging (p. 4, lines 10-16).

One would have had a reasonable expectation of success and been motivated to do so by Southern et al who teach a digitizing scanner that can scan a matrix of several million cells in a few minutes (p. 14, lines 25-27).

Claims 57, 69, 81, 93, 105, 117 and 135-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al. (WO 1989/10977), in view of Rushbrooke et al. (WO 1988/04045) as applied to claims 57, 59, 61-64, 67-71, 76, 79-83, 87-88, 91-93, 96-98, 100-105, 110, 112-117, 122, and 124-134 above, and further in view of Lund et al. (IDS entry #884, filed 05 June 2007).

Claims 135-140 are directed to the immobilization of polymers to beads.

Southern et al. in view of Rushbrooke et al. does not teach the immobilization of a polymer to a bead.

Lund et al. teach a polymer attached to a bead. Lund et al shows the immobilization of distinct polymers to magnetic beads through the covalent attachment

of carbodiimide, cyanogens bromide and diazotization reactions (p. 10864-10866). Lund et al. teach that the beads are very easily and rapidly separated from solutions by using a magnet that saves time (p. 10862).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and software for signal data acquisition and analysis of Rushbrooke et al. and microscope slide microarrays of Southern et al. with the magnetic beads of Lund et al. because Lund et al. teach one can save time by using a magnet to separate the beads very easily and rapidly from solutions.

Response to Arguments

Applicant's arguments filed 24 May 2007 have been fully considered but they are not persuasive. Applicant argues Southern does not teach the limitations of the claims because the claims are patterned after the claims of application 08/897,034 (US Pat 5, 871,928) in which Southern was applied and withdrawn. Upon inspection of the prosecution history of application 08/897,034, it was found that Southern was applied as anticipatory art against the claims of application 08/897,034. In that case, the claims were amended such that Southern did not anticipate the claims and the reference was withdrawn. Applicant does not point out how the claims of the instant application are distinguished over Southern in view of Rushbrooke. As pointed out in the rejection above Southern shows that nucleic acid can be localized to areas of 100 micron by 100 micron and the imaging system of Rushbrooke et al. can provide imaging of areas of 30 microns by 30 microns. The combination of Southern and Rushbrooke make the instantly claimed system obvious. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Obviousness Double Patenting

3. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-131 of U.S. Patent No. 6,403,320 (hereafter the '320 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '320 patent claims an apparatus (reading on the instantly claimed system) and a method which is carried out by a computer (reading on both the instantly claimed software and program) comprising the limitation of the instant application. Furthermore

the specific limitations of the instantly claimed system, program, and software claims are also specifically recited in the claims of the '320 patent. For example, reading on the program and software claims of the instant application reciting a localized area of smaller than $2.5x10^5$ μm^2, the '320 patent recites nucleic acids in claim 1 that are localized in an area of 10^{-2} cm^2 which is 10^4 μm^2 and directly claimed in claim 4 locations having less than 10,000 square microns. One of ordinary skill will readily recognize the CCD detector of the '320 patent intrinsically registers pixel data from the array and that data is collected and stored in a data storage system (reading on a file). Further limitations of the claims in the '320 patent recite the limitations of displaying the data on a video display (cl. 59).

4. Claims 73-74,76, 94-98, 144,149, are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11-17 of U.S. Patent No. 6,403,957 (hereafter the '957 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application recite limitations that are obviated by the claims of the '957 patent. For example, the claims of the '957 patent recite the limitations of scanning a substrate comprising a plurality of different poly nucleotides, movement of a scan stage, receiving image data, collecting and storing image data.

5. Claim 73, 94, and 144 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,545,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system claimed in the '364 patent makes the

limitation of the instant claims obvious. For example, the claims of the '264 patent recite the limitations of receiving image data from a polymer array, a moving scan stage, and image collection.

Provisional Obviousness Double Patenting

6. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of copending Application No. 10/190, 951. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '951 application recite similar limitations as in the instant application. For example, claims 1-20 are directed to a method (interpreted to read on software and programs as being automated methods) and to a system. The method claimed in the '951 application receives and collects intensity data from a polynucleotide array and display the data.

7. Claim 57, 59-60, 65,67-68, 73, 75-77, 78-82, 86-90, 94-98, 108,113, 117, 120, 125, 129, 132, 141, 144, 149, and 156-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-34 of copending Application No. 10/219,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '882 application recite similar limitations as in the instant application. For example, claims 32-34 of the '882 application are directed to a program product (reading on software and a

program) and to a system. The programs receive and collect intensity data from a polynucleotide array and display the data.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 05 June 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is

(571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

19 December 2007

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